

as normally administered are assimilable in the human body, which representations and suggestions were false and misleading since the article failed to disintegrate, so as to permit adequate assimilation of its declared nutrients.

DISPOSITION: 9-12-63: Consent—destruction.

MISCELLANEOUS FOODS

29192. Rodelle Sweet-Tone Preservative. (F.D.C. No. 47217. S. No. 20-828 T.)

QUANTITY: 27 1-gal. jars, at San Antonio, Tex.

SHIPPED: 11-3-61 and 11-4-61, from Denver, Colo, by Rodelle Laboratories, Inc.

LABEL IN PART: (Jar) "Rodelle Sweet-Tone Preservative and Flavor Improver Antiputrefactive Agent to Prevent Growth of Mold and Fermentation Contains: Water, Benzoate of Soda, Propylene Glycol, and Propyl Paraben (A Derivative of Benzoic Acid) Manufactured by Rodelle Laboratories, Incorporated, Denver, Colorado."

LIBELED: 3-12-62, W. Dist. Tex.

CHARGE: 403(a)—while held for sale, the label of the article bore false and misleading representations that the article improved the flavor of foods, and was adequate and effective as a preservative and to prevent growth of mold and fermentation generally in whipped cream goods, cream pie fillings, eclair fillings, pumpkin pie, crusts, candy centers, fondants, and butter creams.

DISPOSITION: On or about 5-23-62, Rodelle Laboratories, Inc., filed a claim to the article. On 6-22-62, the case was transferred to the United States District Court, Dist. Wyo., pursuant to stipulation of the parties. On 8-14-62, an answer to the libel was filed by the claimant. On 12-18-62, the case came on for trial before the court. On 1-11-63, the court rendered the following findings of fact and conclusions of law:

KERR, *District Judge*:

FINDINGS OF FACT

"1. This case involves the seizure of a quantity of . . . 'Rodelle Sweet-Tone Preservative and Flavor Improver' under section 304 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 334.

"2. On March 12, 1962, the United States filed a Libel of Information in the San Antonio Division of the United States District Court for the Western District of Texas, alleging that the above-named product was misbranded while held for sale after shipment in interstate commerce within the meaning of 21 U.S.C. 334(a) and 343(a) in that its labeling, namely, the jar labels, contained statements which represented and suggested that the article improved the flavor of foods and was adequate and effective as a preservative and to prevent growth of mold and fermentation, generally in whipped cream goods, cream pie fillings, eclair fillings, pumpkin pie, crusts, candy centers, fondants, butter creams, and other foods; which statements were false and misleading since they were contrary to fact.

"3. Pursuant to said Libel and process thereunder, 14 gallon jars of the product described in the Libel were seized by the United States Marshal of the above-named district on March 16, 1962.

"4. Rodelle Laboratories, Inc., on May 23, 1962, intervened and filed claim to the goods.

"5. On June 22, 1962, pursuant to stipulation between the Government and Rodelle Laboratories, Inc., the case was transferred to this Court as authorized by 21 U.S.C. 334(b).

"6. On August 14, 1962, Claimant, Rodelle Laboratories, Inc., filed Answer to the Libel and trial by this Court was held commencing December 18, 1962.

"7. The parties stipulated that, on or about November 3 or 4, 1961, the article described in the Libel was shipped from Rodelle Laboratories, Inc., 2700 Arapahoe Street, Denver, Colorado, in interstate commerce via Red Ball Motor

Freight, Inc., and Curry Motor Freight Lines, Inc., to H. T. Lawler and Son, Inc., 731-9 Perez Street, San Antonio, Texas, and that the said consignee received the said shipment.

"8. As stipulated by the parties, the shipment was made to the said consignee for sale in its ordinary course of business to customers for said products such as retailers or bakers.

"9. As stipulated between the parties, on or about January 8, 1962, Loy H. Barber, a Federal Food and Drug Inspector, visited H. T. Lawler & Son, Inc. and purchased a one-gallon jar of Rodelle Sweet-Tone from the shipment described in the Libel. The sample purchased was in every respect, a representative sample of the shipment described in the Libel.

"10. In November, 1962, Mary J. Dolan, a chemist employed by the Food and Drug Administration in its Denver District Laboratory in Denver, Colorado, analyzed a portion of the sample collected by Inspector Barber and found that the product consisted of approximately 28% benzoate of soda; 2% propyl paraben and that the remaining portions of the liquid were propylene glycol and water.

"11. The following statements, among others, appeared on the label of each of the bottles of Rodelle Sweet-Tone involved in this case:

RODELLE SWEET-TONE PRESERVATIVE AND
FLAVOR IMPROVER
ANTIPUTREFACTIVE AGENT TO PREVENT
GROWTH OF MOLD AND FERMENTATION

Following is a partial list of products
Sweet-Tone effectively and economically
protects: (number in parenthesis shows
usual number of ounces used per 100 lbs.)

Bakers' Goods

Whipped cream goods	(5 to 6)
Cream Pie Fillings	(5 to 6)
Eclair Fillings	(5 to 6)
Pumpkin Pie	(6 to 8)
Crusts	(4 to 8)

Confectioners

Candy centers, fondants, butter
creams (4 to 8) . . .

"12. The above label statements represent and suggest that the use of the article in the amounts indicated is effective, i.e. improves the flavor of the foods listed, and is effective as a preservative and to prevent growth of mold and fermentation generally in those foods.

"13. In November, 1962, Bernard F. Surkiewicz, whose expertise in the field of bacteriology was stipulated by the parties, performed several experiments on another portion of the sample collected by Inspector Barber to determine the efficacy of Sweet-Tone as a preservative in custard pie mix, pumpkin pie mix, and chicken salad. He also performed an experiment to determine whether lowering the pH would affect the preservative effect of Sweet-Tone in these products. Mr. Surkiewicz also conducted an experiment to determine the relative effectiveness of sodium benzoate and Sweet-Tone in preserving these products. In these experiments, the criteria for effective preservation was the extent of inhibition in growth of: aerobic microorganisms, and staphylococcus aureus, resulting from the addition of Sweet-Tone to the foods.

"14. These experiments showed that Sweet-Tone preservative, when used in the amounts directed on the label, was not in itself an effective preservative in the products tested. When held for periods of 24 to 48 hours at room temperature, these products, in spite of the addition of Sweet-Tone, developed a level of bacteriological growth which rendered these products a potential danger to health.

"15. Although there is some increase in the preservative effect of Sweet-Tone when utilized in products with lowered pH's, Sweet-Tone's preservative effect on products with a pH in the range covered by the products listed in the Libel is insignificant.

"16. The range of pH of the products listed in the Libel of Information in this case is between 6 and 7.

"17. Dr. Virdell E. Munsey, who is Assistant Chief, Food Research Branch, Division of Food, Food and Drug Administration, Washington, D.C., and whose expertise in the field of food chemistry was stipulated by the parties, conducted two taste tests on another portion of the sample collected by Inspector Barber. In one instance, he used a panel composed of 27 members and in another, 19 members. In these tests he used samples of whipped cream, eclair filling, custard pie filling, and pumpkin pie filling, purchased from a commercial bakery. In each of the two tests, a portion of the bakery products contained Sweet-Tone in the amounts recommended in the label, and the remaining portions of the bakery products did not contain Sweet-Tone. The results of these panel studies showed that no preference was indicated for products containing Sweet-Tone over those that did not contain Sweet-Tone.

"18. Mr. Robert M. Lucero, Vice-President of Rodelle Laboratories, Inc., admitted that the basis of the claim 'flavor improver' on the label of Sweet-Tone was merely that the use of Sweet-Tone in bakery products did not impart a bad taste to the products as did some other preservatives.

"19. Mr. William Tanner, a bacteriologist, was the only expert witness called by the claimant. He admitted that Sweet-Tone was not an effective preservative of products with a pH of 6 or higher. He testified that at a pH between 5 and 6, the article showed a moderate preservative effect and that Sweet-Tone showed a marked preservative effect at a pH of 5 and below.

CONCLUSIONS OF LAW

"1. The Rodelle Sweet-Tone involved in this case is a food within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321(f).

"2. A food is 'held for sale' within the meaning of 21 U.S.C. 334 (a) if it is held in the ordinary course of business.

"3. At the time of seizure by the United States Marshal on March 16, 1962, the Sweet-Tone described in the Libel was held for sale after shipment in interstate commerce within the meaning of 21 U.S.C. 334(a).

"4. The Rodelle Sweet-Tone involved in this case was misbranded within the meaning of 21 U.S.C. 343(a) since its labeling was false and misleading in that the statements on the label of each of the jars of Rodelle Sweet-Tone under seizure represented and suggested that the article improved the flavor of foods listed in the Libel and was adequate and effective as a preservative and to prevent growth of mold and fermentation generally in whipped cream goods, cream pie fillings, eclair fillings, pumpkin pie, crusts, candy centers, fondants, butter creams and other foods and that these statements were false and misleading since the article will not improve the flavor of those foods and is not adequate and effective as a preservative in the foods listed above.

"5. The article is a food which is misbranded while held for sale after shipment in interstate commerce and is condemned and forfeited to the United States pursuant to 21 U.S.C. 334(a)."

On 2-28-63, the Government filed a bill of costs in the sum of \$1,095.74. On 3-5-63, the claimant filed a motion for review of the Government's costs in which the claimant resisted the Government bill of costs for the following reasons:

(1) The per diem charges of Dr. Virdell Munsey and Mr. Bernard F. Surkiewicz were for 6 days. The number of days was excessive in view of the fact that flight time between Washington, D.C., and Cheyenne, Wyo., is less than 1 day each way and the hearing required for this matter extended only 2 days. Per diem charges for each of the witnesses should have been limited to 4 days.

(2) The entire costs of Dr. Virdell Munsey were resisted and should have been dissolved for the reason that he merely testified as to a taste test which he gave panelists, such testing not being the work of a specialist and being so subjective as to be of no value.

(3) The costs of Loy Barber and Mary Dolan were resisted for the reason that the record showed that the claimant stipulated and was willing to stipulate to all things necessary to establish that the product tested by Dr. Virdell Munsey and Mr. Bernard F. Surkiewicz was the identical product which the claimant shipped in interstate commerce and was seized by a United States marshal in Texas, as a consequence of which the testimony of such persons was unnecessary to the proving the Government's case.

On 3-7-63, after the arguments of counsel were heard, the court approved the Government's bill of costs. On 2-26-63, a decree of condemnation was filed which authorized the release of the article under bond for relabeling, conditioned upon execution of the bond within 20 days. On 5-23-63, the article was destroyed, in accordance with terms of the decree.

29193. Canned watercress soup and canned cucumber soup. (F.D.C. No. 48807. S. Nos. 41-843/4 V.)

QUANTITY: 14 cases, each containing 12 13-oz. cans of watercress soup, and 15 cases, each containing 12 13-oz. cans of cucumber soup, at New York, N.Y., in possession of California Preserves, Inc.

SHIPPED: Between 6-2-62 and 12-29-62, from Lake Wales, Fla.

LABEL IN PART: (Can) "Cal Pre Brand Deluxe Watercress Princess Soup [or "Cucumber Royale Soup"] Ingredients: * * * California Preserves, Inc. New York City Distributors."

RESULTS OF INVESTIGATION: Examination showed that the articles contained undeclared artificial colors, namely, FD&C Green No. 2 and FD&C Yellow No. 5 in the watercress soup, and FD&C Green No. 2 in the cucumber soup. Investigation disclosed that these cans had been relabeled by the dealer.

LIBELED: 3-20-63, S. Dist. N.Y.

CHARGE: 402(b)(4)—while held for sale, artificial colors had been added to the articles or mixed or packed therewith so as to make them appear better or of greater value than they were; and 403(k)—the articles contained artificial coloring and they failed to bear labels stating that fact.

DISPOSITION: 4-23-63. Default—destruction.

29194. Corn husks. (F.D.C. No. 49017. S. Nos. 31-921/22 X.)

QUANTITY: 36 bales, each containing 60 lbs., at San Ysidro, Calif.

SHIPPED: 5-10-63, from Tijuana, Mexico, by Humberto Serrano.

LABEL IN PART: (Bale) "Santa Maria Brand Corn Husks * * * Prod. of Mexico Santa Maria, B.C."

LIBELED: 6-27-63, S. Dist. Calif.

CHARGE: 402(a)(3)—contained insects, insect larvae, insect fragments, insect excreta, and insect-damaged corn husks, when shipped.

DISPOSITION: 7-31-63. Default—destruction.

29195. Corn husks. (F.D.C. No. 48372. S. Nos. 63-880 V. 63-883/4 V.)

QUANTITY: 79 72-lb. bales, 176 unlabeled 50-lb. bales, and 63 cases, each containing 12 12-oz. bags, at Los Angeles, Calif.